REMARKS

Claim 89 is pending in the subject application. Claim 89 has been amended herein in order to make certain format changes. No claims have been added or canceled. Support for the language "or a fragment thereof" can be found, *inter alia*, at page 12, lines 17-32, page 14, lines 26-30, Figure 7 and Figure 12A-B. Applicant maintains that the changes to claim 89 raise no issue of new matter, and respectfully request entry of this Amendment. Upon entry of this Amendment, claim 89 will be pending and under examination.

Pursuant to the requirements of 37 C.F.R. §1.121, applicant annexes hereto as Exhibit A claim 89 marked up to show the amendments made herein relative to the previous version thereof.

In view of the amendments to claim 89 and the arguments set forth below, applicant maintains that the Examiner's objections and rejections have been overcome, and respectfully requests that he reconsider and withdraw same.

Rejection Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claim 89 under 35 U.S.C. §112, first paragraph, as containing subject matter allegedly not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. That is, the Examiner asserts that claim 89 does not meet the written description requirement.

In response, applicant respectfully traverses the Examiner's rejection.

Claim 89 provides a purified human MUM-1 protein having the amino acid sequence set forth in SEQ ID NO:14 or a fragment thereof.

The amino acid sequence of SEQ ID NO:14 meets the written description requirement as the Examiner conceded on page two of the June 15, 2001 Office Action. Fragments of the amino acid sequence of SEQ ID NO:14 also meet the written description requirement. Specifically, such fragments are exemplified by the numerous human MUM-1 restriction fragments shown and otherwise described in the specification pages and figures identified above. Hence, applicant was in possession of the invention claimed at the time of filing the subject application.

In view of the above remarks, applicant maintains that claim 89 satisfies the written description requirement of 35 U.S.C. §112, first paragraph.

Rejection Under 35 U.S.C. §101

The Examiner rejected claim 89 under 35 U.S.C. §101 as allegedly not supported by a specific asserted utility or a well-established utility.

In response to the Examiner's rejection of claim 89, applicant respectfully traverses.

Claim 89 provides an isolated human MUM-1 protein or a fragment thereof. In this application, applicant establishes that over-expression of the MUM-1 gene (i.e. over-production of MUM-1 mRNA) correlates with multiple myeloma. Absent a showing to the contrary, one of skill would reasonably conclude that over-production of MUM-1 protein would accompany over-production of its corresponding mRNA.

In his response to applicant's earlier remarks, the Examiner

asserts that such correlation between protein over-expression and mRNA over-expression does not *necessarily* exist. Without conceding the correctness of that position, applicant maintains that MUM-1 protein over-expression would reasonably be expected to correlate with multiple myeloma, based on such correlation observed with MUM-1 mRNA. The mere *possibility* that no correlation between protein over-expression and disease exists is insufficient to support the Examiner's rejection. Hence, it is reasonable for applicant to maintain that over-production of MUM-1 protein correlates with multiple myeloma, and that the Examiner has provided no factual basis for concluding otherwise.

Detecting the over-production of MUM-1 protein provides a means of diagnosing multiple myeloma. The instant protein is useful in this regard, in that it can be used to generate anti-MUM-1 antibodies through established means, while these antibodies in turn can be used to diagnose multiple myeloma in a subject. In short, the claimed protein has a specific and credible utility, because it is useful for stimulating anti-MUM-1 antibody production, which in turn permits the diagnosis of multiple myeloma.

Given the nature of the claimed invention, applicant again maintains that, contrary to the Examiner's assertion, knowledge of the claimed protein's biological activity is *not* required to demonstrate its utility. That is, the claimed protein is useful because, *inter alia*, its over-production is correlative with multiple myeloma. As a result, determining this over-production is all that diagnosing multiple myeloma requires. Any further understanding of MUM-1 protein's function is irrelevant for such purposes.

In view of the above remarks, applicant maintains that claim 89 satisfies the requirements of 35 U.S.C. §101.

Rejection under 35 U.S.C. §112, First Paragraph

The Examiner rejected claim 89 under 35 U.S.C. §112, first paragraph, as allegedly not enabled by the specification. Specifically, the Examiner asserted that one skilled in the art would not know how to use the claimed invention, since it is not supported by either a specific asserted utility or a well established utility.

In response, applicant respectfully traverses the Examiner's rejection. As discussed above, the claimed protein has utility in that detecting its over-production permits the diagnosis of multiple myeloma. Since making the claimed protein and using it to generate antibodies requires only routine materials and methods, applicant maintains that one of ordinary skill would know how to make and use the claimed protein.

In view of the above remarks, applicant maintains that claim 89 satisfies the requirements of 35 U.S.C. §112, first paragraph.

If a telephone conference would be of assistance in advancing the prosecution of the subject application, applicant's undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

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9/17/01

Alan J. Morrison
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Date